JS 44 (Rev. 02/19) JHS

CIVIL COVER SHEET

19-CV-3896

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS
United States of America

(b) County of Residence of First Listed Plaintiff **Philadelphia**
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
John T. Crutchlow, AUSA
United States Attorney's Office
615 Chestnut St. #1250
Philadelphia, PA 19106 215-861-8622

DEFENDANTS
Dr. Stephen C. Padnes

County of Residence of First Listed Defendant **Philadelphia**
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*
Fortunato N. Perri, Jr., Esq.
McMonagle Perri
1845 Walnut St. 19th Fl.
Philadelphia, PA 19103
215-981-0999

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☒ 1 U.S. Government Plaintiff
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*
Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☒ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☒ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

AUG 28 2019

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
21 U.S.C. § 829 et seq. and 31 U.S.C. § 3729 et seq.
Brief description of cause:
Violations of the Controlled Substances Act and False Claims Act

VII. REQUESTED IN COMPLAINT:
☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.
DEMAND $
CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY *(See instructions)*:
JUDGE **Honorable Joel H. Slomsky** DOCKET NUMBER **19cv3636**

DATE 8/28/19
SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

JHS

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

19-3896

DESIGNATION FORM

(to be used by counsel or pro se plaintiff to indicate the category of the case for the purpose of assignment to the appropriate calendar)

Address of Plaintiff: United States Attorney's Office 615 Chestnut St. #1250 Philadelphia, PA 19106

Address of Defendant: c/o Fortunato Perri, Esq. 1845 Walnut Street 19th Fl. Philadelphia, PA 19103

Place of Accident, Incident or Transaction: **Philadelphia, PA**

RELATED CASE, IF ANY:

Case Number: **19cv3636** Judge: **Slomsky** Date Terminated: _____

Civil cases are deemed related when *Yes* is answered to any of the following questions:

		Yes	No
1.	Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court?	☐	☑
2.	Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court?	☑	☐
3.	Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action of this court?	☐	☑
4.	Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual?	☐	☑

I certify that, to my knowledge, the within case ☒ **is** / ☐ **is not** related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: 8/28/19 **John T. Crutchlow, AUSA** *Attorney-at-Law / Pro Se Plaintiff* 201736 *Attorney I.D. # (if applicable)*

CIVIL: (Place a √ in one category only)

A. Federal Question Cases:

- ☐ 1. Indemnity Contract, Marine Contract, and All Other Contracts
- ☐ 2. FELA
- ☐ 3. Jones Act-Personal Injury
- ☐ 4. Antitrust
- ☑ 5. Patent
- ☐ 6. Labor-Management Relations
- ☐ 7. Civil Rights
- ☐ 8. Habeas Corpus
- ☐ 9. Securities Act(s) Cases
- ☐ 10. Social Security Review Cases
- ☑ 11. All other Federal Question Cases
  (Please specify): Controlled Substances Act and FCA

B. Diversity Jurisdiction Cases:

- ☐ 1. Insurance Contract and Other Contracts
- ☐ 2. Airplane Personal Injury
- ☐ 3. Assault, Defamation
- ☐ 4. Marine Personal Injury
- ☐ 5. Motor Vehicle Personal Injury
- ☐ 6. Other Personal Injury *(Please specify):* _____
- ☐ 7. Products Liability
- ☐ 8. Products Liability – Asbestos
- ☐ 9. All other Diversity Cases
  (Please specify): _____

AUG 28 2019

ARBITRATION CERTIFICATION

(The effect of this certification is to remove the case from eligibility for arbitration.)

I, **John T. Crutchlow, AUSA**, counsel of record *or* pro se plaintiff, do hereby certify:

☑ Pursuant to Local Civil Rule 53.2, § 3(c) (2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of $150,000.00 exclusive of interest and costs:

☐ Relief other than monetary damages is sought.

08/28/2019

DATE: _____ *Attorney-at-Law / Pro Se Plaintiff* 201736 *Attorney I.D. # (if applicable)*

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

JHS

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CASE MANAGEMENT TRACK DESIGNATION FORM

United States of America	:	CIVIL ACTION
v.	:	
Dr. Stephen C. Padnes	:	NO. 19-3896

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a Case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a Case Management Track Designation Form specifying the track to which that defendant believes the case should be assigned.

SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:

(a) Habeas Corpus – Cases brought under 28 U.S.C. § 2241 through § 2255. ( )

(b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. ( )

(c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ( )

(d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ( )

(e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) ( )

(f) Standard Management – Cases that do not fall into any one of the other tracks. (X)

August 28, 2019	**John T. Crutchlow, AUSA**	**United States of America**
	Attorney-at-law	**Attorney for**
215-861-8622	**215-861-8618**	**john.crutchlow@usdoj.gov**
Telephone	**FAX Number**	**E-Mail Address**

(Civ. 660) 10/02

AUG 28 2019

JHS

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,	:	
	:	
Plaintiff,	:	
	:	
v.	:	Civil Action No. 19- 3896
	:	
DR. STEPHEN PADNES,	:	
	:	
Defendant.	:	
	:	

COMPLAINT

The United States of America, through the United States Attorney for the Eastern District of Pennsylvania, brings this civil action pursuant to the Controlled Substances Act, 21 U.S.C. § 801, *et seq.* ("CSA"), and the False Claims Act, 31 U.S.C. § 3729, *et seq.*, against Stephen Padnes, M.D. and in support thereof alleges as follows:

PARTIES

1. Plaintiff is the United States of America.

2. Defendant, Stephen Padnes, M.D. ("Padnes"), is a Pennsylvania resident. During the time period of the allegations in this complaint, Padnes was licensed to practice medicine in Pennsylvania and practiced in Philadelphia, Pennsylvania.

3. The Pennsylvania Board of Medicine suspended Padnes's license to practice on August 29, 2016 in response the government's investigation of Padnes. Padnes also surrendered his Drug Enforcement Agency ("DEA") registration and license to prescribe controlled substances.

FAUG 28 2019

JURISDICTION AND VENUE

4. This action is brought by the United States for civil penalties and injunctive relief under the CSA, 21 U.S.C. §§ 801-971, and for civil damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729-33.

5. This Court has subject matter jurisdiction over the alleged CSA civil penalties, 21 U.S.C. § 842, pursuant to 21 U.S.C. § 842(c)(1)(A), and 28 U.S.C. §§ 1331, 1345 and 1355.

6. This Court has subject matter jurisdiction over the alleged CSA injunctive relief, 21 U.S.C. §§ 843(f), 882, pursuant to 21 U.S.C. §§ 843(f), 882, and 28 U.S.C. §§ 1331, 1345.

7. This Court has subject matter jurisdiction over the alleged False Claims Act counts, 31 U.S.C. § 3729, pursuant to 31 U.S.C. § 3732(a), and 28 U.S.C. §§ 1331, 1345, 1355.

8. This Court has personal jurisdiction over Defendant Padnes because he resides in, is located in, transacted business in, and committed the acts at issue in this district.

9. Venue is proper in the Eastern District of Pennsylvania under 28 U.S.C. §§ 1391, 1395, and 31 U.S.C. § 3732(a) because defendant is located, resides, did business, and a substantial part of the events or omissions giving rise to the claims occurred in this district.

STATUTORY AND REGULATORY BACKGROUND

A. The Controlled Substances Act

10. The CSA governs the manufacture, distribution, and dispensing of controlled substances in the United States. The CSA establishes strict guidelines "to ensure a sufficient supply for legitimate medical . . . purpose and to deter diversion of controlled substances to illegal purposes. The substances are regulated because of their potential for abuse and likelihood to cause dependence when abused and because of their serious and potentially unsafe nature if not used under proper circumstances." 75 Fed. Reg. 61613 (Oct. 6, 2010).

11. Under the CSA, there are five schedules of controlled substances – Schedules I, II, III, IV, and V. Controlled substances are scheduled into these levels based upon their potential for abuse, among other factors. Schedule II drugs are those that have a "high potential for abuse" that "may lead to severe psychological or physical dependence," but have "a currently accepted medical use in treatment." 21 U.S.C. § 812(b)(2).

12. Pursuant to legislation and administrative action by the Drug Enforcement Agency ("DEA"), oxycodone, hydrocodone, oxymorphone, methadone, and fentanyl are opioids classified as Schedule II controlled substances. 21 C.F.R. § 1308.12.

13. Pursuant to legislation and administrative action by the DEA, dextroamphetamine, a stimulant, is classified as a Schedule II controlled substance. 21 C.F.R. § 1308.12.

14. Pursuant to legislation and administrative action by the DEA, alprazolam (Xanax), clonazepam, and diazepam are classified as Schedule IV controlled substances. 21 C.F.R. § 1308.14.

15. Oxycodone is a narcotic analgesic that is similar to morphine and is used to treat severe pain, and, even if taken only in prescribed amounts, can cause physical and psychological dependence. Oxycodone is used in pain relief drugs in varying strengths, including 5, 10, 15, 30, 40, 60, and 80 milligram amounts. OxyContin is a brand name medication that contains oxycodone. Even if taken only in prescribed amounts, pills containing amounts as low as 5 milligrams of oxycodone can cause physical and psychological dependence.

16. Methadone is a narcotic analgesic that is also classified as a Schedule II controlled substance, sometimes prescribed under the brand name Dolophine. Methadone pills come in varying strengths, including 5 and 10 milligram amounts. Methadone is used to treat

severe pain, and even if taken only in prescribed amounts, can cause physical and psychological dependence. Methadone is a long-acting opioid and, as such, has pharmacological effects over an extended period of time. Because of this, there is a risk of death and overdose from methadone. However, because it has a slower onset of action associated with less euphoria than shorter-acting opioids, combined with its longer duration of action, methadone is preferred for the suppression of withdrawal in addicted individuals, when used in the context of a comprehensive addiction treatment program.

17. All of the products containing oxycodone and methadone are classified by the DEA as Schedule II controlled substances, which means that they cannot safely be used except under the supervision of a licensed medical practitioner. 21 U.S.C. § 353(b)(1)(A).

18. Title 21, United States Code, Section 841(a)(1), provides that "[e]xcept as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally . . . to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute or dispense, a controlled substance." Title 21, United States Code, Section 829 provides exceptions to this prohibition, including permitting physicians or other authorized health professionals to distribute controlled substances pursuant to a prescription.

19. Title 21, United States Code, Section 802(10), provides that the term "dispense" means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for delivery.

20. Title 21, United States Code, Section 822, explains that every person who prescribes, dispenses, or distributes controlled substances must be registered to do so with the

Attorney General of the United States (with some exceptions, such as delivery persons). The Attorney General has delegated authority to register persons with the DEA. 21 U.S.C. § 822(a).

21. Title 21, United States Code, Section 821, provides that "[t]he Attorney General [of the United States] is authorized to promulgate rules and regulations . . . relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances."

22. The Attorney General of the United States has exercised rulemaking authority regarding the dispensing of controlled substances through the promulgation of 21 Code of Federal Regulations § 1306.04, governing the issuance of prescriptions, which provides that for a "prescription for a controlled substance to be effective [it] must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." Moreover, "[a]n order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. § 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances." 21 C.F.R. § 1306.04(a).

B. <u>The Pennsylvania Code of Professional and Vocational Standards</u>

23. The Pennsylvania Code of Professional and Vocational Standards, Title 49, Chapter 16.92, defines the authority of, and requirements for, physicians licensed by the Commonwealth of Pennsylvania to prescribe or dispense controlled substances. Chapter 16.92 provides in pertinent part:

> (a) A person licensed to practice medicine and surgery in this Commonwealth or otherwise licensed or regulated by the Board, when prescribing, administering or

dispensing controlled substances, shall carry out, or cause to be carried out, the following minimum standards:

> (1) Initial medical history and physical examination. . . . [B]efore commencing treatment that involves prescribing, administering or dispensing a controlled substance, an initial medical history shall be taken and an initial examination shall be conducted unless emergency circumstances justify otherwise. Alternatively, medical history and physical examination information recorded by another health care provider may be considered if the medical history was taken and the physical examination was conducted within the immediately preceding thirty days. The physical examination shall include an evaluation of the heart, lungs, blood pressure and body functions that relate to the patient's specific complaint.
>
> (2) Reevaluations. Among the factors to be considered in determining the number and the frequency of follow-up evaluations that should be recommended to the patient are the condition diagnosed, the controlled substance involved, expected results and possible side effects. For chronic conditions, periodic follow-up evaluations shall be recommended to monitor the effectiveness of the controlled substance in achieving the intended results.
>
> (3) Patient counseling. Appropriate counseling shall be given to the patient regarding the condition diagnosed and the controlled substance prescribed, administered or dispensed. Unless the patient is in an inpatient care setting, the patient shall be specifically counseled about dosage levels, instructions for use, frequency and duration of use and possible side effects.
>
> (4) Medical Records. . . . [C]ertain information shall be recorded in the patient's medical record on each occasion when a controlled substance is prescribed, administered or dispensed. This information shall include the name of the controlled substance, its strength, the quantity and the date it was prescribed, administered or dispensed to a patient. The medical record shall also include a specification of the symptoms observed and reported, the diagnosis of the condition for which the controlled substance is being given and the directions given to the patient for the use of the controlled substance. If the same controlled substance continues to be prescribed, administered or dispensed, the medical record shall reflect changes in the symptoms observed and reported, in the diagnosis of the condition for which the controlled substance is being given and in the directions given to the patient.

C. <u>The Medicare Part D Program and the Medicaid Program</u>

24. Medicare is a federal program administered by the Centers for Medicare & Medicaid Services (CMS), a federal agency within the U.S. Department of Health and Human Services (HHS), to pay for the costs of certain health care services provided to eligible

individuals. Individual entitlement to Medicare is largely based on age, disability, or affliction with end-stage renal disease. 42 U.S.C. §§ 1395-1395lll.

25. One piece of the Medicare program is Medicare Part D, which covers the costs of certain prescription drugs for Medicare beneficiaries. 42 U.S.C. §§ 1395w-101, *et seq.*; 42 C.F.R. § 423.30(a).

26. Medicare provides Part D coverage through plan "sponsors," which are private entities that administer the prescription drug plans on behalf of the federal government.

27. Part D plan sponsors provide reimbursement to pharmacies for drugs, such as oxycodone and methadone, properly dispensed to Medicare beneficiaries enrolled in Part D.

28. Claims submitted for these drugs are recorded and sent to CMS through a prescription drug event (PDE) record, which contains information about the drug dispensed, the beneficiary, the practitioner who prescribed the drug, and payment.

29. CMS makes payments to reimburse the sponsors through (a) monthly estimated payments based upon the beneficiaries enrolled; (b) cost-sharing subsidies for low-income individuals; and (c) payments made annually that reconcile the estimated monthly payments with the allowable costs the sponsor actually incurred. The PDE records are a significant factor influencing the reimbursement amounts.

30. Part D plan sponsors repeatedly certify their compliance with applicable federal laws, regulations, and CMS guidance and certify to the accuracy and truthfulness of the data in the PDE records as a condition of payment.

31. Medicare only covers drugs that are for a "medically accepted indication," which is approved under the Food, Drug, and Cosmetic Act, or as supported in one of the listed compendia. 42 U.S.C. §§ 1395w-102(e), 1396r-8(g)(1)(B), and (k)(6); 42 C.F.R. § 423.100.

Any drugs that do not comply with this requirement render the PDE inaccurate, incomplete, and/or untruthful.

32. If drugs are prescribed for uses that are not "medically accepted indications," they are not covered by Part D. 42 U.S.C. §§ 1395w-102(e), 1396r-8(k)(6).

33. In addition, Part D plan sponsors are only permitted to provide benefits for Part D drugs "that require a prescription if those drugs are dispensed upon a valid prescription." 42 C.F.R. § 423.104(h). A prescription is only valid if it "complies with all applicable State law requirements constituting a valid prescription." 42 C.F.R. § 423.100.

34. Medicaid is a joint federal-state program, also administered for the federal government by CMS, to pay a significant percentage of the costs of certain health care and prescription drugs provided to low-income beneficiaries. 42 U.S.C. §§ 1396-1396w-5. The federal medical assistance percentage contribution to Pennsylvania from fiscal year 2014 to fiscal year 2016 ranged from 51.82% to 53.52%.

35. Pennsylvania's Medicaid program, referred to as "Medical Assistance," is administered by the Pennsylvania Department of Human Services, formerly known as the Department of Public Welfare.

36. As a condition of payment, Pennsylvania's Medical Assistance program only pays for those compensable services and drugs that are "medically necessary." 55 Pa. Code §§ 1101.61, 1121.1, 1121.21.

FACTUAL ALLEGATIONS

A. The Padnes Medical Practice

37. Padnes held a DEA registration allowing him to prescribe controlled substances and was subject to the CSA's requirements at all times from at least January 2000 until approximately August 30, 2016.

38. Padnes surrendered his DEA registration on approximately August 30, 2016.

39. Padnes held a Pennsylvania medical license, from at least January 2000 until approximately August 30, 2016.

40. Padnes solely owned and operated the medical practice of the Psychosomatic Medicine and Pain Rehabilitation Center, Inc. (hereinafter the "Pain Center"), which was located at 1326 Spruce Street, Unit 501, Philadelphia, Pennsylvania, from at least January 2000 until approximately August 30, 2016.

41. From at least January 2000 until approximately August 30, 2016, Padnes was the sole provider of medical services at the Pain Center. He employed others to assist with the administrative responsibilities of operating the Pain Center, but these employees did not participate in or perform any medical services.

42. In 2010 and 2011, Padnes charged approximately $250 per visit. In 2012, Padnes charged approximately $300 per visit. From approximately 2013 to August 30, 2016, Padnes charged approximately $400 per visit. For first time visits, the charge was approximately $100 more than a visit fee.

43. Padnes's Pain Center ledgers show a total gross revenue of at least $2.3 million from 2010 to August 30, 2016.

44. Padnes saw approximately seven patients per day, and the visits were long, often as long as several hours. During the visits, Padnes routinely prescribed controlled substances, including oxycodone and methadone, Schedule II controlled substances.

45. Padnes at times wrote prescriptions for controlled substances, including oxycodone and methadone, Schedule II controlled substances, without a patient visit, but still delivered the prescriptions to the patient, and still charged the patient as if there had been a visit.

46. Based on the government's investigation and Padnes's medical records, from approximately January 2010 to August 30, 2016, Padnes routinely did not perform medical examinations of his patients, did not render diagnoses, did not advise patients of the risks and benefits of treatment, did not reassess his patients receiving chronic opioid therapy, did not monitor his patients for diversion indicators, did not monitor his patients' response to the prescribed medication, and did not monitor the patients' safe use of the prescribed medicine.

47. Padnes routinely did not maintain medical records for his patients as required in the usual course of professional practice.

48. In each year between 2010 and 2016, Padnes routinely wrote prescriptions for controlled substances, including oxycodone and methadone, Schedule II controlled substances, outside the usual course of professional practice and without there being a medically legitimate purpose for these controlled substances to be issued.

49. The HHS's Centers for Disease Control and Prevention (CDC) define morphine milligram equivalent (MME) as the amount of milligrams of morphine an opioid dose is equal to when prescribed. MME is used by practitioners to calculate the total amount of opioids a patient receives, accounting for differences in opioid drug type and strength.

50. The CDC's guidance on prescribing opioids for chronic pain states that clinicians should carefully reassess evidence of individual benefits and risks when considering increasing dosage to greater than 50 MME per day, and should avoid increasing dosage to greater than 90 MME per day or carefully justify dosages exceeding that threshold.

51. Guidelines published by the Commonwealth of Pennsylvania in July of 2014 stated that more than 100 MME per day is not associated with improved pain control and is associated with increased risk of harm to patients.

52. Padnes often prescribed Schedule II opioids to patients over extended periods of months or years that amounted to daily MME doses exceeding 500 MME per day, and in some cases exceeding 1,000 MME per day, without maintaining medical records consistent with the usual course of medical practice.

53. In each year from 2013 through 2016, and likely earlier, Padnes knew that prescriptions he wrote without a legitimate medical purpose were paid for by federal health care programs, including Medicare Part D and Medicaid.

54. On numerous occasions between 2013 to 2016, Padnes completed and signed prior authorization forms that were submitted to federal health care plans justifying the controlled substances he prescribed to the plan beneficiaries so that the plans would pay for the drugs.

55. In the four years between 2013 and 2016, Medicare Part D paid over $750,000 to fill more than 4,000 prescriptions issued by Padnes for controlled substances.

56. In the four years between 2013 and 2016, Pennsylvania's Medicaid program paid over $575,000 to fill more than 4,000 prescriptions issued by Padnes for controlled substances.

B. Representative Padnes Patients

R.D. and Customer # 1

57. Padnes regularly provided R.D. with prescriptions for controlled substances, including oxycodone, methadone, and Xanax from 2010 until 2016.

58. Padnes's records indicate that R.D. personally paid Padnes over $20,000 during that period, including $3,400 in 2013, $4,600 in 2014, $4,300 in 2015, and $1,600 in 2016.

59. R.D. told Padnes that she had a fractured vertebrae and Chronic Obstructive Pulmonary Disease.

60. Padnes did not maintain medical records substantiating either alleged condition.

61. Padnes did not maintain medical records in the usual course of medical practice for the vast majority of his interactions with R.D. or the vast majority of prescriptions he wrote for R.D.

62. Padnes's records do not reflect that he reassessed R.D., monitored R.D. for diversion indicators, monitored R.D.'s response to the prescribed medication, or monitored R.D.'s safe use of the prescribed medication.

63. In the approximately nine months between January 2, 2013 and October 1, 2013, Padnes provided at least 18 prescriptions for R.D. for Schedule II controlled substances, including nine prescriptions for a total of 8,400 Methadone (10 milligram (mg)) tablets and nine prescriptions for a total of 1,305 Oxycodone (30mg) tablets. Pharmacies filled each of these prescriptions.

64. Together, these prescriptions provided for a morphine equivalent dose exceeding an average of 1,000 MME per day.

65. In the approximately eight months between December 8, 2014 and August 17, 2015, Padnes provided at least 26 prescriptions for R.D. for Schedule II controlled substances, including 13 prescriptions for a total of 12,600 methadone (10mg) tablets and 13 prescriptions for a total of 1,650 oxycodone (30mg) tablets. Pharmacies filled each of these prescriptions.

66. Together, these prescriptions provided for a morphine equivalent dose exceeding 1,300 MME per day.

67. R.D. sold methadone and oxycodone tablets that R.D. obtained with prescriptions provided by Padnes to drug dealers.

68. On October 29, 2015, an individual (Customer # 1) entered the Padnes medical office without R.D. and stated he was a relative of R.D. The office manager handed Customer # 1 five prescriptions made out in the name of R.D. in exchange for $400 in cash. The prescriptions were comprised of two for 75 oxycodone (30mg) tablets, one for 90 Xanax (1mg) tablets, and two for 600 (10mg) methadone tablets. Padnes did not meet with Customer # 1 nor did office staff attempt to verify Customer # 1's identity.

69. Padnes provided those prescriptions in exchange for cash, without any corresponding office visit or examination of R.D.

70. On November 24, 2015, R.D. introduced Customer #1 to Padnes at the Padnes medical office.

71. On seven occasions between December 21, 2015 and June 29, 2016, Padnes provided Customer # 1 prescriptions for controlled substances, including, but not limited to, seven prescriptions for oxycodone (15mg) tablets and seven prescriptions for methadone (10mg) tablets.

72. Customer # 1 paid to Padnes $500 in cash the first time Padnes provided prescriptions to Customer # 1 and $400 in cash each subsequent time.

73. On or about February 22, 2016, March 23, 2016, April 21, 2016, and June 29, 2016, Customer # 1 met with Padnes at the Padnes medical office without R.D. being present. Each time, Padnes provided three prescriptions for R.D. to Customer # 1 in exchange for $400 cash. Each time, these prescriptions were for 150 oxycodone (30mg) tablets, 90 Xanax (1mg) tablets, and 1200 methadone (10mg) tablets.

74. On each such occasion, Padnes exchanged R.D.'s prescriptions for cash without any corresponding office visit or examination of R.D.

75. At each of these visits, Padnes also provided prescriptions to Customer #1 in exchange for an additional $400 in cash. Each time, these prescriptions included oxycodone, methadone, and cyclobenzaprine.

76. Padnes did not maintain medical records of the majority of his encounters with Customer # 1, never performed a physical examination of Customer # 1, never required Customer # 1 to undergo urine drug testing, and never verified Customer # 1's medical history.

77. None of the prescriptions for controlled substances that Padnes issued for R.D. at any time were issued for a legitimate medical purpose or in the usual course of medical practice.

78. None of the prescriptions for controlled substances that Padnes issued for Customer # 1 at any time were issued for a legitimate medical purpose or in the usual course of medical practice.

R.F.

79. R.F. began seeing Padnes in the 1980s following a back surgery.

80. Padnes prescribed Schedule II opioids to R.F. from that time until 2014.

81. R.F. personally paid Padnes $11,500 between 2010 and 2014, including $2,900 in 2012, $2,600 in 2013, and $1,500 in 2014.

82. In the three years between June of 2011 and June of 2014, Padnes provided to R.F., and R.F. filled, prescriptions for 57,759 methadone (10mg) tablets, an average exceeding 50 tablets per day; 7,518 oxycodone (30mg) tablets, an average exceeding 6 tablets per day; 14,910 OxyContin (80mg) tablets, an average exceeding 13 tablets per day; and 1,266 transdermal fentanyl (100 mcg/hour) patches, an average exceeding one patch per day.

83. Together, these prescriptions provided for a morphine equivalent dose exceeding an average of 4,000 MME per day.

84. Padnes did not maintain medical records in the usual course of medical practice for the vast majority of his interactions with R.F. or the vast majority of prescriptions he wrote for R.F.

85. Padnes's records do not reflect that he examined R.F., reassessed R.F., monitored R.F. for diversion indicators, monitored R.F.'s response to the prescribed medication, or monitored R.F.'s safe use of the prescribed medication.

86. R.F. sold the vast majority of the opioid tablets he obtained with the prescriptions from Padnes during this time period to a drug dealer who then sold them on the street.

87. R.F. was arrested in mid-2014 for selling opioid pills he obtained with the prescriptions he received from Padnes.

88. None of the prescriptions for controlled substances that Padnes issued to R.F. at any time were issued for a legitimate medical purpose or in the usual course of medical practice.

89. R.F. was a Medicare beneficiary who participated in the Part D program.

90. On multiple occasions, Padnes submitted prior authorization forms to R.F.'s Medicare Part D plan purporting to justify the prescriptions he wrote for R.F. for controlled substances. Padnes therefore knew that Medicare Part D paid to fill the prescriptions he wrote for R.F.

91. Between May 1, 2013 and July 31, 2014, Medicare Part D paid over $100,000 to pharmacies to fill 130 prescriptions for controlled substances that Padnes issued for R.F. without a legitimate medical purpose. Padnes knowingly caused these false claims to be submitted to the Medicare Part D program.

T.F.

92. Padnes regularly prescribed a significant quantity of Schedule II controlled substances to T.F., including oxycodone and methadone, from at least as early as 2010 and continuing until at least January of 2015.

93. Padnes's records indicate that T.F. personally paid Padnes over $14,000 during that period, including $3,050 in 2012, $3,640 in 2013, $3,350 in 2014, and $950 in 2015.

94. Prior to seeking prescriptions from Padnes, T.F. received many prescriptions for Schedule II controlled substances from Jeffrey Bado, D.O. ("Bado"). Bado was convicted in December of 2016 for illegally prescribing opioids in violation of the CSA.

95. Between April 24, 2014 and January 12, 2015, Padnes issued to T.F., and T.F. filled at least: 20 prescriptions for a total of 15,340 methadone (10mg) tablets, an average of approximately 50 tablets per day; 9 prescriptions for a total of 480 OxyContin (80mg) tablets, an average of approximately 8 tablets per day; 11 prescriptions for a total of 2,310 oxycodone (30mg) tablets, an average exceeding five tablets per day; and three prescriptions for a total of 360 clonazepam (1mg) tablets, an average exceeding one tablet per day.

96. The opioid prescriptions that Padnes issued to T.F. from June of 2011 through January of 2015 provided for an average daily morphine equivalent dose exceeding 1,700 MME per day.

97. The opioid prescriptions that Padnes issued to T.F. from January 30, 2014 through January 12, 2015 provided for an average morphine equivalent dose exceeding 2,000 MME per day.

98. Padnes did not maintain medical records in the usual course of medical practice for the vast majority of his interactions with T.F. or the vast majority of the prescriptions he wrote for T.F.

99. Padnes maintained only scant, undated, and barely legible handwritten notes of interactions between Padnes and T.F. Those records did not comport with the usual course of medical practice.

100. Padnes's medical records do not indicate that Padnes reassessed the significant quantity of opioids he prescribed to T.F., monitored T.F. for diversion indicators, monitored T.F.'s response to the opioids he prescribed, or monitored T.F.'s safe use of the prescribed medication.

101. Accordingly, none of the prescriptions that Padnes issued for T.F. were issued for a legitimate medical purpose and none were issued in the usual course of medical practice.

102. On January 4, 2017, approximately two years after receiving her last prescription from Dr. Padnes, T.F. died in Philadelphia at 52 years of age. The City of Philadelphia Medical Examiner determined that the cause of death was "acute drug intoxication."

103. T.F. was a Medicaid beneficiary.

104. Medicaid paid over $20,000 to fill dozens of prescriptions for controlled substances issued by Padnes for T.F. from 2013 through 2015.

105. Padnes personally completed and signed multiple prior authorizations for Keystone First, T.F.'s Medicaid plan, purporting to justify the prescriptions for the Schedule II controlled substances that he issued for T.F.

106. Padnes therefore knew that T.F. was a Medicaid beneficiary and that the Medicaid program paid to fill the Schedule II opioid prescriptions that he issued for T.F.

107. Padnes knowingly caused these false claims to be submitted to the Medicaid program.

D.M.

108. Padnes regularly prescribed a significant quantity of Schedule II controlled substances to D.M., including oxycodone and methadone, from at least as early as 2012 and continuing until June of 2016.

109. Between May 1, 2014 and May 24, 2016, Padnes issued, and D.M. filled, at least 62 prescriptions for a total of 20,800 methadone (10mg) tablets and 24 prescriptions for a total of 2,640 oxycodone (30mg) tablets.

110. These opioid prescriptions provided for an average morphine equivalent dose exceeding 975 MME per day.

111. Padnes maintained only scant, undated, and barely legible handwritten notes of interactions between Padnes and D.M. Those records did not comport with the usual course of medical practice.

112. Padnes did not maintain medical records in the usual course of medical practice for the vast majority of his interactions with D.M. or the vast majority of prescriptions he wrote for D.M.

113. Padnes's medical records do not indicate that Padnes ever examined D.M., reassessed the significant quantity of opioids he prescribed to D.M., monitored D.M. for diversion indicators, monitored D.M.'s response to the opioids he prescribed, or monitored D.M.'s safe use of the prescribed medication.

114. On June 10, 2016, the day after his last visit to Padnes, D.M. died in Philadelphia at 60 years of age. The City of Philadelphia Medical Examiner determined that the cause of

death was "drug intoxication" resulting from "excessive intake and/or accumulation of medication." The manner of death was ruled to be an accident.

115. T.F. and D.M. are two of at least six former long term patients of Padnes who ultimately died of a drug overdose between 2014 and 2017, either while they were Padnes patients or later; these patients also included: O.A., who died at 45 years of age on March 25, 2014; M.B., who died at 30 years of age on May 13, 2014; N.D. who died on January 17, 2016 at 51 years of age; and K.B., who died on January 28, 2017 at 46 years of age.

E.L. and C.L.

116. Padnes prescribed Schedule II opioids, including methadone and oxycodone, to both E.L. and his daughter C.L. from at least as early as 2012 and continuing through at least 2015 for E.L. and 2016 for C.L.

117. Padnes's records indicate that E.L. personally paid Padnes over $12,000 from 2012 to 2015, including $2,780 in 2013, $3,900 in 2014, and $2,770 in 2015.

118. Padnes's records indicate that C.L. personally paid Padnes over $15,000 from 2012 to 2016, including $3,500 in 2013, $4,400 in 2014, $5,300 in 2015, and $2,000 in 2016.

119. On April 26, 2014, E.L. submitted a urine sample for a urine drug test ordered by Padnes. E.L.'s urine tested positive for cocaine metabolites, indicating that E.L. used cocaine, and amphetamines in addition to the methadone and oxycodone Padnes prescribed. Padnes received the results.

120. In the usual course of medical practice, a urine sample indicating simultaneous use of illicit drugs, including cocaine, and prescription opioids requires the attention and action of the prescribing physician.

121. Padnes's records reflect no recognition of the test results, no discussion with E.L. regarding the test results, no other mention of E.L.'s use of cocaine and amphetamines, no change in the prescriptions for oxycodone and methadone that he provided to E.L., and no other urine or other drug tests. This does not comport with the usual course of medical practice.

122. In the fourteen months between May 22, 2014 and July 28, 2015, Padnes issued to E.L., and E.L. filled, at least: 45 prescriptions for a total of 21,600 methadone (10 mg) tablets and 17 prescriptions for a total of 1,960 oxycodone (30 mg) tablets.

123. Together, these prescriptions provided for a morphine equivalent dose exceeding an average of 1,500 MME per day.

124. Padnes did not maintain medical records in the usual course of medical practice for the vast majority of his interactions with E.L. or the vast majority of prescriptions he wrote for E.L.

125. Padnes maintained only scant, undated, and barely legible handwritten notes of interactions between Padnes and E.L. that do not comport with the usual course of medical practice.

126. Padnes's medical records do not indicate that Padnes ever physically examined E.L., reassessed the significant quantity of opioids he prescribed to E.L., monitored E.L. for diversion indicators, monitored E.L.'s response to the opioids he prescribed, or monitored E.L.'s safe use of the prescribed medication.

127. Accordingly, none of the prescriptions that Padnes issued for E.L. were issued for a legitimate medical purpose and none were issued in the usual course of medical practice.

128. E.L. was a Medicaid beneficiary.

129. Medicaid paid over $5,000 to fill over 100 prescriptions for controlled substances issued by Padnes for E.L. from May 16, 2013 through July 28, 2015.

130. Padnes maintained in his office file a copy of E.L.'s insurance information from Keystone First, E.L.'s Medicaid plan, and completed at least one prior authorization for Keystone First justifying the prescriptions for the Schedule II controlled substances that he issued for E.L.

131. Padnes therefore knew that E.L. was a Medicaid beneficiary and that the Medicaid program paid to fill the Schedule II opioid prescriptions that he issued for E.L. Padnes knowingly caused these false claims to be submitted to Medicaid.

132. Beginning at least as early as December of of 2012, Padnes regularly prescribed large quantities of methadone and oxycodone to C.L.

133. On April 26, 2014, C.L. submitted a urine sample for a urine drug test ordered by Padnes. C.L.'s urine test was positive for metabolites consistent with the use of benzodiazepines, a Schedule IV controlled substance with brand names including Valium, in addition to the methadone and oxycodone prescribed by Padnes. Padnes received the results.

134. The simultaneous use of benzodiazepines and prescription opioids is potentially dangerous, with risks that include death.

135. Padnes's records reflect no mention of prescribing benzodiazepines to C.L., no recognition of the urine test results, no discussion with C.L. regarding the test results, no change in the prescriptions for oxycodone and methadone that he provided to C.L., and no other urine or other drug tests. This did not comport with the usual course of medical practice.

136. In the nineteen months between May 22, 2014 and December 23, 2015, Padnes issued to C.L., and C.L. filled, at least: 23 prescriptions for a total of 18,060 methadone (10 mg) tablets and 22 prescriptions for a total of 2,580 oxycodone (30 mg) tablets.

137. Together, these prescriptions provided for a morphine equivalent dose exceeding an average of 1,000 MME per day.

138. Padnes did not maintain medical records in the usual course of medical practice for the vast majority of his interactions with C.L. or the vast majority of prescriptions he wrote for C.L.

139. Padnes maintained only scant, undated, and barely legible handwritten notes of interactions between Padnes and C.L. that do not comport with the usual course of medical practice.

140. Padnes's medical records do not indicate that Padnes ever physically examined C.L., reassessed the significant quantity of opioids he prescribed to C.L., monitored C.L. for diversion indicators, monitored C.L.'s response to the opioids he prescribed, or monitored C.L.'s safe use of the prescribed medication.

141. Accordingly, none of the prescriptions that Padnes issued for C.L. were issued for a legitimate medical purpose and none were issued in the usual course of medical practice.

J.M. and L.M.

142. Padnes prescribed opioids to both J.M. and L.M., husband and wife.

143. Padnes regularly prescribed opioids for L.M. for more than a decade. Between January of 2011 and September of 2016, Padnes issued, and L.M. filled, prescriptions for over 100,000 methadone (10mg) tablets and over 5,700 oxycodone (15mg) tablets.

144. Between May 20, 2014 and October 29, 2015, Padnes issued at least 42 prescriptions to L.M. for a total of 27,462 methadone (10mg) tablets and 23 prescriptions for a total of 1,884 oxycodone (15mg) tablets. L.M. filled each of these prescriptions.

145. Together, these prescriptions provided for an average daily morphine equivalent dose exceeding 1,500 MME per day.

146. Between May 20, 2014 and October 29, 2015, Padnes issued at least 25 prescriptions to J.M. for a total of 8,176 methadone (10mg) tablets and 24 prescriptions for a total of 1,168 oxycodone (15mg) tablets. J.M. filled each of these prescriptions.

147. Together, these prescriptions provided for an average daily morphine equivalent dose exceeding 450 MME per day.

148. Padnes did not maintain medical records in the usual course of medical practice for the vast majority of his interactions with L.M. or the vast majority of prescriptions he wrote for L.M.

149. Padnes did not maintain medical records in the usual course of medical practice for the vast majority of his interactions with J.M. or the vast majority of prescriptions he wrote for J.M.

150. Padnes ordered a urine drug test for J.M. and L.M. which were completed based on a samples obtained on October 29, 2015. The results were faxed to Padnes on November 4, 2015.

151. L.M.'s October 29, 2015 urine drug test detected methadone and cocaine, but did not detect oxycodone.

152. J.M.'s October 29, 2015 urine drug test did not detect either methadone or oxycodone.

153. Padnes received the results on or about November 4, 2015, and knew or should have known that these results indicated that J.M. was not taking the methadone and oxycodone as prescribed, that L.M. was not taking the oxycodone as prescribed, and that L.M. was also using cocaine.

154. In the usual course of medical practice, a urine sample indicating simultaneous use of illicit drugs, including cocaine, and prescription opioids requires the attention and action of the prescribing physician.

155. The absence of oxycodone from either test, and the absence of methadone from J.M.'s test, could suggest the medications were not needed, were being illegally diverted, and/or that J.M. and L.M. were overusing the medications after filling the prescriptions. A prescribing physician acting in the usual course of medical practice would have determined the reason, taken appropriate action, and maintained medical records documenting the physician's findings and actions.

156. Padnes's records reflect no recognition of the test results, no discussion with J.M. or L.M. regarding the test results, no other mention of L.M.'s use of cocaine, no change in the prescriptions for oxycodone and methadone that he provided to either J.M. or L.M., and no other urine or other drug tests. This did not comport with the usual course of medical practice.

157. After L.M.'s urine test, from November 30, 2015 through September 16, 2016, Padnes prescribed, and L.M. filled, at least 22 prescriptions for a total of 14,950 methadone (10mg) tablets and 12 prescriptions for a total of 1,288 oxycodone (15mg) tablets.

158. Together, these prescriptions provided for an average daily morphine equivalent dose exceeding 1,600 MME per day.

159. Padnes's medical records do not indicate that Padnes reassessed the significant quantity of opioids he prescribed to L.M., monitored L.M. for diversion indicators, monitored L.M.'s response to the opioids he prescribed, or monitored L.M.'s safe use of the prescribed medication.

160. After J.M.'s urine test, from November 30, 2015 through August 16, 2016, Padnes prescribed, and J.M. filled, at least 11 prescriptions for a total of 5,400 methadone (10mg) tablets and 11 prescriptions for a total of 675 oxycodone (15mg) tablets.

161. Together, these prescriptions provided for an average daily morphine equivalent dose exceeding 600 MME per day.

162. Padnes's medical records do not indicate that Padnes ever physically examined J.M., reassessed the significant quantity of opioids he prescribed to J.M., monitored J.M. for diversion indicators, monitored J.M.'s response to the opioids he prescribed, or monitored J.M.'s safe use of the prescribed medication.

163. Accordingly, none of the prescriptions that Padnes issued for L.M. or J.M. were issued for a legitimate medical purpose and none were issued in the usual course of medical practice.

164. L.M. and J.M. were Medicare beneficiaries who participated in the Part D program.

165. On multiple occasions, Padnes submitted prior authorization forms to L.M.'s and J.M.'s Medicare Part D plans purporting to justify the prescriptions he wrote for L.M. and J.M. for controlled substances. Padnes therefore knew that Medicare Part D paid to fill some or all of the prescriptions he wrote for L.M. and J.M.

166. Between May 1, 2013 and August 31, 2016, Medicare Part D paid over $7,800 to pharmacies to fill 227 prescriptions for controlled substances that Padnes issued for L.M. without a legitimate medical purpose. Padnes knowingly caused these false claims to be submitted to the Medicare Part D program.

167. Between May 1, 2013 and August 31, 2016, Medicare Part D paid over $2,000 to pharmacies to fill over 120 prescriptions for controlled substances that Padnes issued for J.M. without a legitimate medical purpose. Padnes knowingly caused these false claims to be submitted to the Medicare Part D program.

COUNTS 1-426:
Unlawful Distributing and Dispensing of Controlled Substances in Violation of the Controlled Substances Act (21 U.S.C. §§ 842(a)(1), 829)

168. The United States re-alleges the above paragraphs as if fully set forth herein.

169. Defendant Padnes is subject to the requirements of Part C of the CSA, 21 U.S.C. § 822.

170. As alleged above, Padnes wrote hundreds of prescriptions for, and therefore distributed and/or dispensed, controlled substances without a legitimate medical purpose and outside the usual course of professional practice, in violation of 21 U.S.C. § 829(a), (b) and 21 C.F.R. § 1306.04, including, but not limited to:

a. 26 prescriptions for R.D. for Schedule II controlled substances issued between December 8, 2014 and August 17, 2015, comprised of: 13 prescriptions for methadone (10mg) tablets and 13 prescriptions for oxycodone (30mg) tablets.

b. 36 prescriptions for Schedule II controlled substances issued to T.F. between May 1, 2014 and January 12, 2015, comprised of: 18 prescriptions for methadone

(10mg) tablets, 8 prescriptions for OxyContin (80mg) tablets, and 10 prescriptions for oxycodone (30mg) tablets.

c. At least 86 prescriptions for Schedule II controlled substances issued to D.M. between May 1, 2014 and June 10, 2016, comprised of: 62 prescriptions for methadone (10mg) tablets, and 24 prescriptions for oxycodone (30mg) tablets/

d. 62 prescriptions for Schedule II controlled substances issued to E.L. between May 1, 2014 and July 28, 2015, comprised of: 45 prescriptions for methadone (10 mg) tablets and 17 prescriptions for 1,960 oxycodone (30 mg) tablets.

e. 45 prescriptions for Schedule II controlled substances issued to C.L. between May 1, 2014 and December 23, 2015, comprised of: 23 prescriptions for methadone (10 mg) tablets and 22 prescriptions for oxycodone (30 mg) tablets.

f. 99 prescriptions for Schedule II controlled substances issued to L.M. from May 1, 2014 through September 16, 2016, comprised of: 64 prescriptions for methadone (10mg) tablets and 35 prescriptions for oxycodone (15mg) tablets.

g. 71 prescriptions for Schedule II controlled substances issued to J.M. from May 1, 2014 through August 16, 2016, comprised of: 36 prescriptions for methadone (10mg) tablets and 35 prescriptions for 8 oxycodone (15mg) tablets.

h. Additional prescriptions for controlled substances that Padnes issued to patients without a legitimate medical purpose and outside the usual course of medical practice between May 1, 2014 and September 1, 2016.

COUNT 427:
Causing the Presentation of False Claims:
31 U.S.C. § 3729(a)(1)(A)

171. The United States re-alleges the above paragraphs as if fully set forth herein.

172. In the four years between 2013 and 2016 Medicare Part D paid over $750,000 to fill more than 4,000 prescriptions issued by Padnes for controlled substances.

173. In the four years between 2013 and 2016, Pennsylvania's Medicaid program paid over $575,000 to fill more than 4,000 prescriptions issued by Padnes for controlled substances.

174. At all relevant times Padnes routinely wrote prescriptions for controlled substances, including the Schedule II controlled substances oxycodone and methadone, outside the usual course of professional practice and without a legitimate medical purpose.

175. Padnes routinely completed prior authorization forms for federal health care plans, and therefore knew that a large percentage of the prescriptions for controlled substances that he wrote were paid for by federal health care programs, including Medicaid and Medicare.

176. Accordingly, Padnes knowingly caused the presentment of false and fraudulent claims for payment or approval of prescriptions to Medicare and Medicaid, in violation of 31 U.S.C. § 3729(a)(1)(A), upon the pharmacies' submission of their claims to Medicare and Medicaid.

177. By virtue of these false and/or fraudulent claims, the United States has suffered damages and, therefore, is entitled to treble damages under the False Claims Act, to be determined at trial, plus a civil penalty for each false claim submitted.

PRAYER FOR RELIEF

WHEREFORE, the United States of America demands judgment against defendant Stephen Padnes as follows:

1. Civil penalties of up to $25,000 per violation of the CSA occurring on or before November 2, 2015, 21 U.S.C. § 842(c)(1)(A); and civil penalties of up to $64,820 per violation of the CSA occurring after November 2, 2015, 28 C.F.R. § 85.5;

2. Injunctive relief, pursuant to 21 U.S.C. §§ 843(f), 882, permanently enjoining Padnes from prescribing all controlled substances, as defined by the CSA and its implementing regulations;

3. Damages sustained by the United States, trebled, as mandated by the False Claims Act, 31 U.S.C. § 3729(a)(1);

4. Civil penalties of between $5,500 and $11,000 for each false claim presented on or before November 2, 2015, 31 U.S.C. § 3729(a)(1); 28 C.F.R. § 85.3(a)(9); and civil penalties of between $11,181 and $22,363 for each false claim presented after November 2, 2015, 28 C.F.R. § 85.5; and

5. Post-judgment interest, costs, and such other and further relief as the Court deems just and equitable.

Jury Demand

The United States hereby demands a trial by jury of all issues so triable pursuant to Rule 38 of the Federal Rules of Civil Procedure.

Respectfully submitted,

WILLIAM M. McSWAIN
United States Attorney

GREGORY B. DAVID
Assistant United States Attorney
Chief, Civil Division

CHARLENE KELLER FULLMER
Assistant United States Attorney
Deputy Chief, Civil Division

JOHN T. CRUTCHLOW
Assistant United States Attorney
United States Attorney's Office
615 Chestnut Street, Suite 1250
Philadelphia, PA 19106
(215) 861-8622
john.crutchlow@usdoj.gov

Dated: August 28, 2019